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04-14-03 #6 DAC

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Neto et al.	Examiner:	Weiss, J. F.
Title:	Secretion Suctioning Device And Kit For Intubated Patients	Serial No.:	09/838,863
Filed:	April 20, 2001	Ref. No.:	70317.1200

PETITION UNDER 37 C.F.R. § 1.78(a)(3) TO ACCEPT A CLAIM OF PRIORITY DELAYED UNINTENTIONALLY

TO: Box DAC
Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicant respectfully submits this Petition under 37 C.F.R. § 1.78(a)(3) to accept a claim of priority delayed unintentionally for the above-referenced application, where the claim of priority is made under 35 U.S.C. § 365(c) to a prior filed international application designating the United States of America, Application No. PCT/BR99/00084, filed on October 13, 1999, which in turn claims priority to a Brazilian patent application, Application No. 9804529-6, filed on October 23, 1998. In accordance with 37 C.F.R. § 1.78(a)(2), Applicant will amend the specification to claim priority to both of the above-mentioned prior-filed applications.

Applicant encloses along with this Petition a copy of the reference document, PCT/BR99/00084, as required by 37 C.F.R. § 1.78(a)(3)(i), and the surcharge set forth in 37

C.F.R. § 1.17(t). Applicant believes the fee submitted is sufficient for the grant of this Petition, but authorizes any additional fees to be charged to Hughes Hubbard & Reed Deposit Account No. 08-3264. In accordance with 37 C.F.R. § 1.78(a)(3)(iii), Applicant submits the statement below that the delay in making the priority claim was unintentional.

Applicant respectfully requests that this Petition be considered and granted.

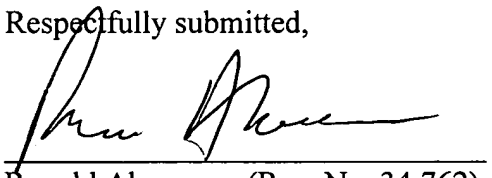
STATEMENT UNDER 37 C.F.R. §1.78(a)(3)(iii)

Applicant filed the original patent application, Brazilian Patent Application No. 9804529-6, on October 23, 1998. On October 13, 1999, Applicant timely filed international patent application no. PCT/BR99/00084, claiming priority to the prior-filed Brazilian patent application. On April 20, 2001, before expiration of the 30-month deadline, Applicant filed the instant patent application in the United States, with the intent to claim priority to both the above-mentioned PCT application and the Brazilian priority document. Applicant referenced and claimed priority to the Brazilian priority document in the Declaration filed along with the U.S. application on April 20, 2001. However, although the as-filed application in the United States was copied directly from the published PCT application and contained the reference number of the PCT application in the header of each page of the specification document, Applicant inadvertently and unintentionally failed to particularly designate and claim priority of the PCT application under 35 U.S.C. § 365(c). Attorney for Applicant discovered the inadvertent and unintentional failure to claim priority of the PCT application upon receipt of the first substantive Office Action, mailed on April 2, 2003, in which the present application was rejected under 35 U.S.C. § 102(d) over Applicant's Brazilian application.

Applicant hereby claims priority under 35 U.S.C. § 365(c) of the instant application, U.S. Patent Application Serial No. 09/838,863, to International Application No. PCT/BR99/00084, filed on October 13, 1999, which in turn claims priority to Brazilian Patent Application Serial No. 9804529-6, filed on October 23, 1998. Attorney for Applicant states herein that the delay in making this priority claim was unintentional, and respectfully requests that the Petition under 37 C.F.R. § 1.78(a)(3) herein be considered and granted.

Dated: April 11, 2003

Respectfully submitted,



Ronald Abramson (Reg. No. 34,762)
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PTO/SB/17 (01-03)
Approved for use through 04/30/2003. OMB 0651-0032
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FEE TRANSMITTAL for FY 2003

Effective 01/01/2003. Patent fees are subject to annual revision.

☑ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 1,300

Complete if Known	
Application Number	09/838,863
Filing Date	April 20, 2001
First Named Inventor	Neto et al.
Examiner Name	Weiss Jr., Joseph
Art Unit	4421
Attorney Docket No.	70317.1200

METHOD OF PAYMENT *(check all that apply)*

☑ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

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Deposit Account Name: 08-3264

The Commissioner is authorized to: *(check all that apply)*

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FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	750	2001	375	Utility filing fee	
1002	330	2002	165	Design filing fee	
1003	520	2003	260	Plant filing fee	
1004	750	2004	375	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($) 0

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

	Extra Claims		Fee from below		Fee Paid
Total Claims		-20** =		X	=
Independent Claims		- 3** =		X	=
Multiple Dependent					=

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	84	2201	42	Independent claims in excess of 3
1203	280	2203	140	Multiple dependent claim, if not paid
1204	84	2204	42	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 0

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FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	410	2252	205	Extension for reply within second month	
1253	930	2253	465	Extension for reply within third month	
1254	1,450	2254	725	Extension for reply within fourth month	
1255	1,970	2255	985	Extension for reply within fifth month	
1401	320	2401	160	Notice of Appeal	
1402	320	2402	160	Filing a brief in support of an appeal	
1403	280	2403	140	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,300	2453	650	Petition to revive - unintentional	
1501	1,300	2501	650	Utility issue fee (or reissue)	
1502	470	2502	235	Design issue fee	
1503	630	2503	315	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	750	2809	375	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	750	2810	375	For each additional invention to be examined (37 CFR 1.129(b))	
1801	750	2801	375	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) Petition to Accept Unintentionally Delayed Claim for Priority 1,300

*Reduced by Basic Filing Fee Paid **SUBTOTAL (3)** ($) 1,300

SUBMITTED BY				(Complete *(if applicable)*)	
Name (Print/Type)	Ronald Abramson	*Registration No. (Attorney/Agent)*	34,762	*Telephone* 212-837-6000	
Signature				*Date*	4-10-03

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/BR99/00084

(22) International Filing Date: 13 October 1999 (13.10.99)

(30) Priority Data:
9804529-6 23 October 1998 (23.10.98) BR

(61) Related by Addition to Earlier Applications or Grants
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Filed on Not furnished
MK Not furnished (POA)
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MW Not furnished (POA)
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NZ Not furnished (POA)
Filed on Not furnished
SI Not furnished (POA)
Filed on Not furnished

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(81) Designated States: AL (Utility model), AM (Utility model), AT, AT (Utility model), AU (Petty patent), AZ, BA, BB, BG (Utility model), BY, CA, CH, CN (Utility model), CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, EE (Utility model), ES (Utility model), FI, FI (Utility model), GB, GE (Utility model), GH, GM, HR, HU (Utility model), ID, IL, IS, JP (Utility model), KE (Utility model), KG (Utility model), KP (Inventor's certificate), KR (Utility model), KZ (Utility model), LC, LK, LR, LS (Utility model), LT, LU, LV, MD (Utility model), MG, MK, MN, MW, MX (Utility model), NO, NZ, PL (Utility model), PT (Utility model), RO, RU (Utility model), SD, SE, SG, SI, SK, SK (Utility model), SL, TJ (Utility model), TM, TR (Utility model), TT, UA (Utility model), UG, US, UZ (Utility model), VN (Utility model), YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

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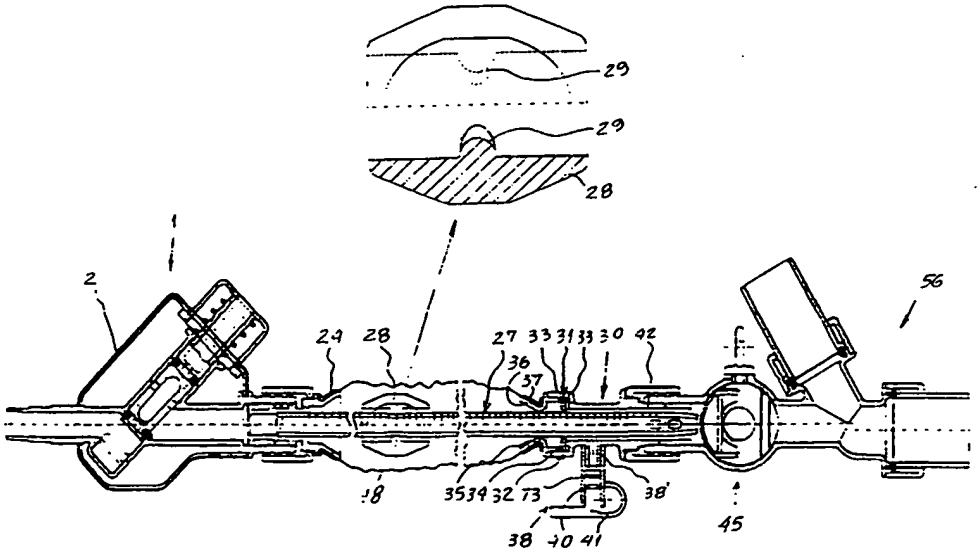
(54) Title: SECRETION SUCTIONING DEVICE AND KIT FOR INTUBATED PATIENTS



(57) Abstract

This invention is a secretion, a suction device, and kit for intubated or tracheostomized patients including a suction valve (1) having a body (2) with a chamber (3) where a selective obstruction device (4) is assembled. The device further includes a spherical valve (45) which selectively opens or closes a passage for a probe (25) through a patient/ventilator connection (56). The kit allows for the correct positioning of the suction device, including a plastic sheathing (65), and a tube for disposal of the suction device.

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SECRETION SUCTIONING DEVICE AND KIT FOR INTUBATED PATIENTS

This report relates to a secretion suctioning device for intubated or tracheostomized patients, as well as to a secretion suctioning device for intubated or tracheostomized patients, maintaining mechanical ventilation. The device, part of said kit, contains a suctioning valve, a sealing/instillation set, a spherical connection set (including a connection for the patient/ventilator tube), and a packaging that includes a plastic sheating and a connector for disposal of the material .

Such invention relates to probes or catheters for tracheal suctioning, more specifically, the mechanical ventilation of a patient's respiratory system and the suctioning of the fluids accumulated in the patient's trachea or bronchi.

Particularly, this patent relates to a new apparatus (related method) to jointly maintain the ventilation, aspirate secretions from and instillate solutions into the patient's respiratory system, and wash the catheter, with no risks to the patient.

This report takes into consideration the following documents: 1.174.397 dated 12/1969 - United Kingdom 128/351; 3.902.500 dated 9/1975 - Dryden 604/171X; - 3.991.762 dated 11/76 - Radford 604/119;

4.351.328 dated 9/1982 - Bodai 128/202.16; 4.569.344 dated 2/1986 - Palmer 128/207.16; 4.638.539 dated 1/1987 - Palmer 128/207.16; 4.696.296 dated 9/1987 - Palmer 128/207.16; 4.805.611 dated 2/1989 - Hodgkins 128/207.14; 4.825.859 dated 5/1989 - Lambert 128/207.16; 4.834.726 dated 5/1989 - Lambert 604/281; 4.836.199 dated 6/1989 - Palmer 128/207.16; 4.838.255 dated 6.1989 - Lambert 128/207.16; 4.850.350 dated 7/1989 - Jackson 128/207.16; 4.872.579 dated 10/1989 - Palmer 128/207.16; 4.938.199 4.938.741 dated 7/1990 - Lambert 604/19; 4.967.743 dated 11/1990 - Lambert 128/207.16; 4.981.466 dated 1/1991 - Lambert 604/19; 5.025.806 dated 6/1991 - Palmer et al 128/207.14; 5.029.580 dated 7/1991 - Radford et al 128/207.14; 5.065.754 dated 11/1991 - Jansen 128/200.26; 5.073.164 dated 12/1991 - Hollister 604/43; 5.080.646; 5.083.561 dated 1/1992 - Russo 128/207.16; 5.088.486 dated 2/1992 - Jinotti 128/207.14; 5.107.829 dated 4/1992 - Lambert 128/202.16; 5.125.893 dated 6/1992 - Dryden 604/54; 5.133.345 dated 7/1992 - Lambert 604/171; 5.134.996 dated 8/1992 - Bell 128/207.14; 5.139.018 dated 8/1992 - Brodsky et al 128/207.14; 5.140.983 dated 8/1992 - Jinotti 128/207.14; 5.220.916 dated 6/1993 - Russo 128/207.16; 5.255.676 dated 10/1993 - Russo 128/207.14; 5.269.756 dated 12/1993 - Dryden 604/54; 5.279.549 dated 1/1994 - Ranford 604/34; 5.325.851 dated 7/1994 - Raynolds et al 128/204.16; 5.337.780 dated 8/1994 - Kee 137/381; 5.354.267 dated 10/1994 - Niermann et al 604/32; 5.368.017 dated 11/1994 - Sorenson et al 128/200.26; 5.445.141 dated 8/1995 - Kee et

al 128/203.12; 5.449.348 dated 9/1995 - Dryden 604/71; 5.460.613 dated 10/1995 - Ulrich et al 604/118; 5.490.503 dated 2/1996 - Hollister 128/205.12; 5.582.165 dated 12/1996 - Bryan et al 128/207.14; 5.598.840 dated 2/1997 - Iund et al 128/207.14; 5.642.276 dated 7/1997 - Oewns et al 128/200.26; 5.645.048 dated 7/1997 - Brodsky et al 128/202.27; 5.715.815 dated 2/1998 - Lorenzen et al 128/207.14; and the following scientific publications: 1. Carlon GC, Fox SJ, Ackerman NJ. Evaluation of a closed-tracheal system. Crit Care Med 1987; 15:522-525; 2. Clark AP, Winslow EH, Tyler DO, et al. Effects of endotracheal suctioning on Mixed venous saturation and heart rate in critically ill adults. Heart lung 1990; 19:522-557; 3. Cobley M, Atkins M, Jones PL. Environmental contamination during tracheal suction. Anaesthesia, 1991, volume 46, pp. 957-961; 4. Czarnik RE, Stone KS, Everhart CC, et al. Differential effects of continuous versus intermittent suction on tracheal tissue. Heart lung 1991; 20: 144-151; 5. DePew CL, Moseley MJ, Clark EG, Morales CC. Open vx closed endotracheal suctioning: a cost comparison. Critical Care Nurse, Feb. 1994, pp. 94-100; 6. Deppe AS, Kelly W, Thol LL et al. Incidence of colonization, nosocomial pneumonia, and mortality in critically ill patients using a Trach Care ® closed-suction system versus and open-suction system: Prospective, randomized study. Crit Care Med 1990; 18:1389-1393; 7. Grossi AS. Closed endotracheal suction system for the prevention of hypoxemia. Rev Esc Enfermagem USP 1995; 29:1 26-33; 8. Johnson KL, Kearneu PA, Johnson

SB, et al. Closed versus open endotracheal suctioning: Cost and physiologics consequences. Crit Care Med 1994; 22:658-666; 9. Mattar JA, Baruzzi ACA, Diament D; et al. A clinical comparison between cardiac output measured by thermodilution technique and noninvasive thoracic electrical bioimpedance. Acute Care 1986; 12:58-60; 10. Mattar JA, Bastos JT, Silva LA, et al. The effects on oxygen transport with varying respiratory flow waveforms in critically ill patients. Crit Care Med 1997; 25(Suppl) A36; 11. Mattar JA, Shoemaker WC, Diament D, et al. Sistolic and diastolic time intervals in critically ill patients . Crit Care Med 1991; 19: 1392-1398; 12. Mattar JA, Sproesser, Jr AJ, Gomes MV. A comparative study of oxygen transport ruring open and closed methods of tracheal suctioning. Int & Crit Care Dig 1992; 11:57-58; 13. Mattar JA. Noninvasive cardiac output determination by thoracic electrical bioimpedance. Int & Crit Care Dig 1988; 7:14-18; 14. Raymond SJ. Normal saline instillation before suctioning helpful or harmful. A review of the literature. American Journal of Critical Care, July 1995, issue number 4, number 4, pp., 267-271; 15. Ritz R, Scott LR, Coyle MB, Pierson DJ. Contamination of a multiple-use suction catheter in a closed-circuit system compared to contamination of a disposable, single use single suction catheter. Respiratory Care, November 1986, volume 31, number 11. pp. 1086-1091.

As it is known by the medical professional area, the critically ill ICU [Intensive Care Unit] patient under mechanical ventilation has a

physiologic balance that keeps him alive, and depends on an acceptable blood and tissue oxygenation level provided by the ventilatory support.

During the tracheal suctioning periods routinely performed in an intermittent manner, for the twenty-four hours of the day, an important blood oxygen desaturation may occur, which can lead to cardiac arrhythmias, low cardiac output, blood pressure variation, and other disturbances. Should this set of disturbances be analized in a suctioning episode, the transitory abnormal physiologic situation reverts itself when reinstalling the effective ventilation, without apparent permanent damage; however, considering that the patients under mechanical ventilation have a prolonged stay at the ICU, the accumulated sum of these shortages may be harmful and may have an influence on the survival time.

Furthermore, during the pulmonary secretion suctioning procedure, tube contamination may be caused where the catheter is to be introduced in the patient, the user as well may be contaminated with the secretion expelled from the patient's lung. Cobley et al, Deppe et al and Ritz et al discuss the environmental contamination issue, cross contamination, and other means of contamination during the tracheal suctioning.

One of the first proposed solutions in the past, in order to overcome these problems, was to sheath the catheter in a flexible glove, to prevent

it from being touched. This apparatus is described by the English patent 1.174.397, from 1969, granted to the National Research Development Corporation. This apparatus, nevertheless constituting a breakthrough in the sterile handling of suctioning probes, did not resolve the problem of hypoxia, during and after the suctioning, among other problems that continued without solution.

Dryden, in 1975, obtained the North American patent under number 3.902.500, with an apparatus mentioned in almost all subsequent patents, related to simultaneous suctioning and ventilation. Dryden proposed the catheter sheathing the glove, be sealed from both sides. Beyond that, the oxygen could be introduced inside the glove, which would inflate, thus directioning oxygen to the patient, through the compression of the glove. The patent also proposed an adapter which would allow a connection to a ventilator, thus allowing ventilation simultaneously with the suctioning procedure.

In 1976, Radford was granted the North American patent under number 3.991.762, that proposed a mechanism connected to the patient, which could operate for ventilation and suctioning, including a irrigation route, a medicine introduction route and a valve-like device to trigger the vacuum, among other innovations. This system, however, presented a series of problems, such as: excessively expensive components, excessive weight over the endotracheal tube, possible inadequate aspiration, mechanical handling potentially

harmful to the endotracheal tube, sheating impairment of the endotracheal probe, assembling and disassembling difficulties, possible expelling of the secretion to the atmosphere, etc.

Later, a series of patents were granted in the United States, especially to Darrel Palmer and Richard C. Lambert, having Ballard Medical Products as the holder, the most important being as following: 4.569.344; 4.638.539; 4.696.296; 4.825.859; 4.834.726; 4.836.199; 4.838.255; 4.872.579; 4.938.199; 4.938.741; 4.967.743; 4.981.466; 5.025.806; 5.080.646; and 5.133.345.

These patents intend to overcome the previous techniques' imperfections, comprising an apparatus (and a related method) that integrated in a single item the ventilating capacity to ventilate the patient and to aspirate fluids from his trachea and bronchi. It also looked to reduce traumas and risks for the patient, to avoid inadequate aspiration caused either by the patient himself or by the nurse or nurse's aid, and to avoid secretions from being expelled into the atmosphere during the periods when suctioning was not being performed. Furthermore, the inventions intended to be more feasible, from an economic point of view, than the previous ones.

From these and other patents, a product is currently marketed worldwide with the tradename "Trach Care", available in several models (adult and neonatal) and gauges: 05, 06, 08, 10, 12, 14, 16 and 18

"Fr", with details such as double lumen (for irrigation), "directional tip" (for selective suctioning of the bronchi), a special model for tracheostomized patients, and so on.

Another series of patents were also granted in the United States, having Smiths Industries Medical Systems as its holder, some of which are listed as follows: 5.073.164 (William H. Hollister); 5.134.996 (Craig J. Bell); 5.460.613 (Karl Ulrich and Thomas Devlin); and 5.490.503 (William J. Hollister).

Smiths Industrial Medical Systems introduced in the market the "Stericath", also presented in several gauges and models, currently marketed worldwide.

One, of the various intentions of these new inventions, was to solve the air opening within the catheter sheathing plastic glove problem, which led the glove to inflate, and made the subsequent use of the device more complicated.

From the Trach Care and Stericath products marketing, the tracheal closed suctioning system use became, little by little, routine in hospitals worldwide, starting in the 80's.

Simultaneously, in several comparative clinical trials between closed and open suctioning, the advantage of closed suctioning over the open one was demonstrated, including higher patient survival levels, which nowadays justifies the routine use

of such method in substitution to the classic open suctioning.

After reviewing various essays on this subject, Mattar et al (1986) had the opportunity to develop a nation wide study, involving three ICUs, including a total of 22 patients upon mechanical ventilation, aiming at the oxygen transport rate confirmation during the classic open suctioning ("OS") and sequentially, on the same patient, during the closed suctioning ("CS"). The group had already performed other studies, aproaching physiologic variables that, direct or indirectly were important as well to the global analysis of the results.

Some of the most important comparative studies on "OS" versus "CS" will be later on discussed.

Carlton and his medical nursing staff from the Anaesthesia and Intensive Medicine Department of Memorial Sloan-Kettering Cancer Center (New York), studied in 1987 the benefits of "CS" in twenty patients, ventilated with the use of variable levels of final expiratory positive pressure ("FEPP"), which in "OS" is known to drop to zero. The measures performed before and after both suctioning types, performed sequentially, were: carbonic gas blood partial pressure ($PaCO_2$), oxygen arterial saturation (SaO_2), and oxygen pressure alveolus - arterial gradient (A-a O_2). It was statistically demonstrated that these oxygen rates lowered only in "OS",

implying that the lowering in "FEPP" as one of those principally responsible for the reported variation. In "CS", since the "FEPP" levels are maintained, there was no significant lowering of these rates. The authors also mention as a potential advantage the prevention of secretion dissemination into the environment.

A broad study in Houston, Texas hospitals, developed in clinical and surgery ICUs and coordinated by Deppe, comprised a total of 84 patients, studied concerning the nosocomial pneumonia incidences and, especially the survival rate. No differences were reported between "OS" and "OS" related to the pneumonia incidence, however, there was a distinct difference on the survival rate (studied up to 900 hours of hospital internment) with "CS".

During the same year (1990), another group formed by a nursing staff of 4 hospitals from Texas University (Austin) and Texas University (Arlington), developed a meticulous and well conducted study supported by the NIH - National Institute of Health, with the object of comparing "OS" and "CS", relating to the oxygen saturation in mixed venous blood from the pulmonary artery (SvO_2) and heart rate ("HR") in 189 patients. The main finding was the increase of "SvO_2" in "CS", while there was a lowering during the procedure in "OS", noticing also a advantageous persistency of supra-elevated values up to 2 minutes after the "CS" termination.

Statistically, there were no

differences between the relationship of "HR" studied in both groups, and other important points were the preservation of the "FEPP" level and the same adjustment of the ventilator in "CS", while in "OS", in many cases, there was a loss of control of the adjustment prior to the ventilator disconnection to the "OS"'s procedure, and obviously, "FEPP" levels suppression (Clark et al).

Czarnit et al, from the Columbus Nursing Research Center, Ohio, studied the anatomicopathological changes in both "OS" and "CS" methods in 12 dogs, with special regards to the tracheal mucosa ulceration and necrosis at several levels, not describing significant differences in both groups studied. There is no reference to physiologic or hemodynamic data, and such experimental findings may not always be applied to the medical practice.

A more recent study (1994) by Johnson et al, in trauma units in Lexington, New York, comprised 35 patients with multiple traumas, divided into "OS" (16 patients) and "CS" (19 patients), with a total of 276 suctioning procedures (127 "OS" and 149 "CS"). The data studied before and after the procedures were: average arterial pressure ("AAP"), heart rate ("HR"), presence of arrhythmia, arterial and venous oxygen saturation (SaO_2 and SvO_2), nosocomial pneumonia incidence and daily patient procedure costs. The final results of the study show: I. Higher "AAP" in "OS"; II. equal "HR", but persistent elevated "HR" 30 seconds after "OS"'s termination; III.

Lower arrhythmia incidence in "CS"; IV. PaO_2 and PvO_2 lowering in "OS" and increase in "CS"; V. There were no differences between the pneumonia rates; VI. The operational cost of "OS" was US$ 1,88/patient/day greater than in "CS", besides occupying higher nursing time than "OS".

In Máttar et al (1992), the comparative study variable was the oxygen transport rate ("O_2TR"). During the protocol elaboration, the authors profited from the previous experience with the cardiac rate ("CR") noninvasive monitoring method, joined to continuous "SaO_2" data through pulse oxymeter, and the hemoglobin dosage, usually present is such patients. Summarizing, that normal "O_2TR" is around 600 ml/O_2/min/m^2 of body surface and it is estimated by the formula: "O_2TR"= "CR" (L/min/m^2) x Hb (g/dL0 x 13,6 x $SatO_2$(%) x 10. The "O_2TR" values were selected at the suctioning beginning (B), termination (T), and the maximum (Mx) and Minimum (Mn) values were also estimated during the entire procedure. "OS" and "CS" were alternated and consequently applied to the same patient, and the results, as average values, are summarized below:

	(B)	(T)	(Mx)	(Mn)
"O_2TROS" ml/min/m^2	352	322	364	305
"O_2TRCS" ml/min/m^2	355	35	365	334

All the variables studied, with an influence on the survival rate of the critically ill patient under mechanical ventilation, may undergo changes, according to the suctioning procedure clinical

status, especially relating to the cardiac cycle conditions and type of ventilation flow applied, as highlighted by Máttar (1991 and 1997).

In 1995, Grossi (USP Nursing School) published a review study on the practical aspects of the subject, proving that "CS" was more effective than "OS" in the maintenance of the PaO_2 in most of the patients studied.

Johnson et al and Depew et al, among other studies identified in the technical literature, made a comparison of the cost/benefit relationship between open and closed suctioning systems, arriving to the conclusion that the closed suctioning happens to be less expensive than the open one.

This brief literature review is to show the scientific and financial acceptance of the use of tracheal suctioning through closed system procedures, comparing it to the now considered old fashioned open system.

Currently, a series of other products are marketed as Closed Tracheal Suctioning Systems, that are proposed to be better than those previously existing: Sherwood Medical Company; MedCare Medical Group (East Swansey, NH, USA), under the name ACCS™ (Airway Catheter Cartridge System) Jinotti™; BLD Medical Products (Dallas, Texas, USA), under the name Neo-Link plus™ - Mallinckrodt, under the name Hi-Care; Allegiance Healthcare Corporation (McGaw Park, Illinois,

USA, under the name Trach-Eze™; Hudson RCI, under the name Cath-Guide Closed Suction Catheter; Vital Signs Ind., under the name Iso-Cath™.

Several patents are also referenced in the beginning of this report, concerning these products, or even related inventions, though not available in the market.

Some of the innovations proposed in these patents are: more comfortable apparatus for the patient, with a cost lower than the currently marketed; different valve systems to trigger the suctioning; systems totally closed during the catheter wash-out (which are opened solely during the passage of the catheter to perform the suctioning); instillation routes positioned in different parts of the system; spinning connections, and in elbow shape; etc.

Aiming at the patent hereby proposed, it is advisable to make comments on some patents mentioned herein.

The US patent 4.805.611 was granted in 1989 to Harold M. Hodgkins. His main concern is with the suctioning valve position, in his appraisal, too distant from the patient, that can lead to inadequate aspiration. His proposal is to approximate the system connection valve to the patient, so that the introduction does not imply the moving of the valve and other parts of the system. Although interesting, this proposal presents problems, for instance, during the introduction of the

catheter, which will be bent at all times, causing possible suctioning distress. The inadequate aspiration matter, in the patent hereby proposed, is overcome by the closed chamber and the visual indication for the operator, as well as the spherical set minimizes the moving effects of the set on the patient.

The US patent 5.083.561, granted in 1992 to Ronald D. Russo, presents an interesting discussion on the suctioning valve structure different from the prior technique. In Russo's point of view, there is no need for a valve, likewise proposed in the previous inventions, but only a system positioned externally to the probe secretion flow for the vacuum, which triggers the vacuum. He proposes then a clamp system to trigger the vacuum and stop its flow, so that the secretion does not pass through its interior, thus avoiding the secretion accumulation within the valves, which, in Russo's opinion, would lead to the impaired functioning or even the valve suctioning capacity interruption. Russo's concern seems to be quite pertinent, but the proposal, however apparently feasible, presents enormous difficulties in its applicability, in terms of engineering.

This invention proposes an internal closure system to the suctioning valve, which prevents the secretion accumulation within the valves, thus avoiding the problems pointed out by Russo, in a simpler and more economic manner.

The US patent 5.255.676,

granted to Ronald D. Russo on October 26th, 1993 proposes, among other advantages, the use of an irrigation route in a diaphragm shape, which, besides being cheaper than the other means proposed by the copetitors, avoids the oxygen loss that occurs when the irrigation means are left open.

However, the diaphragm used as a substitute for the irrigation route presents some risks, for instance, the wearing of the material, handling difficulties with syringes or I.V. tubes, etc. The patent herein proposed suggests the maintenance of the irrigation route, because of the facility it presents regarding the I.V. tube or syringe handling, but reinforced by the use of an internal diaphragm to the irrigation route, in addition to the protection against oxygen loss through the closed chamber.

An interesting patent, granted to James F. Bryan and Blaine E. Black (US 5.582.165) in 1996, proposes the invention of a catheter, sheatered in plastic, that can be connected to a vacuum source and to an endotracheal tube, making a closed system. The interesting point of the invention is that the plastic itself, used to protect the catheter (and the user) becomes plastic packaging for the catheter disposal after its use. For the very first time, as far as it is known, appears the concern, associated with the invention of a new model of Tracheal Suctioning Closed System, with the disposal of the system itself, taking into consideration the possible infection carriers that may be created by the material

after its use. However, the invention appears to be very complex and not feasible in its assembly, and even in the catheter disposal. On the other hand, the invention herein discussed, concerns also the disposal, but proposes a safer and more feasible system than that of Bryan and Beck.

The US patent 5.645.048 granted to David I. Brodsky and Harry O. Olsen in 1997 presents an innovation concerning the state of the prior technique. It presents the possibility of using as disposable only a central part of the kit, being able to be used for either the part connecting to the patient, or the part connecting to the vacuum. In addition to proposing a lowering in the cost, with the parts of the kit keeping for longer, the invention further proposes a connecting route between both ends of the central disposable part of the kit, so that the disposal of the material is more hygienic.

The use of only a part of the System as disposable showed to be an economic, feasible, and safe proposal, and it has been already used by some manufacturers. However, there is no appropriate indication for the user that the system is closed or open, which disqualifies the invention, since the system may stay open, disabling the closed chamber function. The patent herein proposed presents a series of innovations in this respect: a sphere as a separation between the disposable and fixed parts of the system; a color indicator (red and green) which allows the user to identify whether the system is closed or opened; an easy handling key, which allows the

opening and the closure of the system, without keeping the user's hand busy during the suctioning procedure, and etc.

Raymond's et al study proposes that the use of saline solution instillation be discontinued, because of the damages it may cause to the patients. Though we do not completely share Raymond's conclusion, as we could agree with the use of the instillation to liquefy the secretion to be suctioned, for instance, we believe that a closed system should not allow that the saline solutions used for the probe wash-out end up being aspirated by the patient. In the case of the currently marketed products, noted previously, it ends up being necessary to lift the patient's head during the probe wash-out procedure, to prevent the saline solution from going down the endotracheal tube, which, obviously, causes uncalculated damages to the patient's recovery, besides the distress caused to both the patient and the user. The proposal presented by this patent includes a sphere with color indicator, which closes the system with a visual indication and completely seals off the probe reflux for the patient, thus allowing the catheter wash-out without any contact whatsoever with the patient.

The concern with the disposal of the system, especially due to the high levels of hospital contamination that the scientific community tries to overcome, in global terms, has become essential for every medical product. Our proposal implies a series of inventions: a connector coupled to the kit packaging, which

allows both system ends to be connected in its interior, thus avoiding the possibility of secretion being expelled after the connection; a plastic coupled to the kit packaging, in which the disposable part of the system should be inserted every twenty-four hours (and as well as the part that remains longer, at the time that it should be changed), and which will be closed and disposed of (thus preventing any type of contamination to be transmitted to the environment, users, patients, hospital waste collectors, etc).

Patent 5.715.815, granted to Lorenzen et al, suggests a seal-shaped filter, to preserve the system sterilization. However, the invention seems to be insufficient, since the invention hereby proposed suggests a much more effective sealing system.

There is no concern, in all the inventions surveyed, regarding the air flow that goes from the ventilator to the patient. None of the proposals of the prior techniques status considers a physiologic air flow, by presenting sketches that have direct influence on the air pathway to the patient.

The proposed patents also concerned with this factor, proposing a sketch for the tube-ventilator connector, which allows a much more physiologic flow than the previous inventions.

As it is observed through the different parts that compose our proposal for a "CS" kit, there are several innovating possibilities that the

previous devices that were considered state-of-the-art do not consider. In addition, such an invention proposes to be simpler and less expensive than the current technique.

It is expected that, with the routine implementation of the "CS" system hereby proposed, there are savings with regards the previous inventions (which creates consequences for the patients, to health care institutions, medical plans, etc.), greater ease in the system handling by the nurse, higher survival rates especially with patients under mechanical ventilation with prolonged stays in ICUs such as those with multiple traumas, respiratory infections, postoperative complications, neurologic disturbances, and other conditions.

Taking into consideration the description of the current technique, and the problems previously noted, this invention overcomes and/or relieves the above mentioned problems, and consists of an endotracheal secretion suctioning kit, maintaining the mechanical ventilation of the patient, allowing the probe wash-out in a manner that prevents the saline solution from passing to the patient, with a colored sphere indicating the opening and closure of the system, vacuum triggering anatomic valve, sealing system through a three-ring set, and accessory components for the safe disposal of the material after use. The kit, among other functions, allows savings through the disposal (after 24 hours) of the set for installation/sealing, keeping the valve and the sphere

connection for longer; disposal with no contamination risks for the patient, users and all people who might handle the product as hospital waste; laminar air flow sent to the patient by the ventilator, which creates a more physiologic ventilation procedure; safe sealing and complete in several parts, protecting thus the patient, users and environment from possible contamination; handling facility for the users; accessory coupling possibility (such as filters, humidifiers, fixtures, secretion collection flasks, etc.), all essential during the suctioning procedure; visual identification for the users through colors, indicating whether the system is open or closed; prevention of secretion accumulation risks within the suctioning valve, through a sealing ring system; etc.

One of the objects of the invention is to provide a tracheal suctioning kit which maintains the mechanical ventilation of the patient, overcoming several problems found in the previous techniques.

Another object of this invention patent is to provide a closed system tracheal suctioning kit, containing a central disposable set each 24 hours, with visual marking for the user when the system is closed or open, thus avoiding the absorption of undesired saline solution by the patient, and avoiding the system from remaining inadvertantly open, allowing endoscopy (or other) exams to be performed, keeping the patient ventilated without the need for completely disconnecting

the kit, among other functions. The set consists of a colored sphere, with red and green colors, indicating whether the system is closed or open. The sphere has an easily adjustable selection key, which allows the user to open or close the system and then free his hand for other functions during the suctioning procedure. One of the parts of the set connects to the ventilator and to the patient, through a double swivel connection. The other part of the set connects to the sealing/instillation set. When the system is open, the probe passage through the sphere's interior is possible, in order to allow the suctioning. When the probe is returned to its initial position, the sphere is closed, thus isolating the probe and the patient's instillation route.

Another object of this invention is to provide a tracheal suctioning kit, maintaining the mechanical ventilation, with a suctioning triggering anatomic valve system, with total sealing of the system, thus avoiding the secretion accumulation which would eventually damage the functioning of said kit.

Another object of this invention is to provide a tracheal suctioning kit, maintaining the mechanical ventilation, with total sealing of the system, with a special three internal ring sealing system.

Another object of this invention is to provide a tracheal suctioning kit, maintaining the mechanical ventilation, which allows the

effective and safe disposal of the material from the moment the kit (or part of it) is removed from the patient, until the moment it becomes hospital waste, thus avoiding several types of contamination (for the environment, the users, the patient himself, and all those who handle hospital waste, etc.). The sealing/instillation set should be disposed of every 24 hours. Each end should be inserted into a connector, which comes with the packaging, thus avoiding the secretion contained in the set from leaking and acting as an infection agent. The set, already protected by the disposable connector, should also be inserted into a special plastic sheating, which also accompanies the packaging of the kit, and avoids the contamination created by the material when it becomes hospital waste.

Another object of this invention is to provide a kit for tracheal suctioning maintaining the mechanical ventilation, with a design that allows a laminar air flow that proceeds from the ventilator to the patient, thus avoiding turbulences that eventually become harmful for the maintenance of the artificial respiration.

Another object of this invention is to provide a tracheal suctioning kit, maintaining the mechanical ventilation, which presents larger handling facility for the users. From the moment the spherical selecting key is handled, opening or closing the system, there is no need for the user to keep his hand busy with the said key, thus releasing said hand for any other

necessary activity during the suctioning procedure or probe wash-out. The anatomic valve system allows greater esae in the vacuum triggering, also creating less fatigue for the system users.

Finally, another object of this invention patent is to provide a tracheal suctioning kit, which allows the maintenance of the mechanical ventilation, more economical than the prior inventions. The fact that only the sealing/instillation set is disposable, the facilities presented for the problem solving, presented by the previous inventions (but whose proposals were unfeasible, from an engineering point of view, or even extremely expensive), the simplicity of the proposed ideas, etc. make this invention more cost effective than those previous known.

Following, the device itself will be described in a detailed manner, regarding the sketches listed below, of which:

figure 1 illustrates an overview of the proposed device;

figure 2 illustrates an overview of this device, which is showed in cross section, with enlarged detail;

figure 3 illustrates an enlarged detail taken from figure 2, which demonstrates the suction valve;

figure 4 illustrates a detail in enlarged section, which is taken from figure

2, demonstrating the spinning connection for the ventilator and the patient, with a sphere system;

figure 5 illustrates a schematic and section view of the sphere shaped selecting key, being the same on its closure condition;

figure 6 illustrates a view of the kit set, which comprises the proposed device, along with other components intended to make the safe disposal possible, all of those duly boxed in one package;

figure 7 illustrates a view that exemplifies, in a schematic manner, the possibility of disposal of the device hereby proposed, more specifically, the above mentioned figure 7 illustrates the refill disposal operation of such a device, which comprises its probe and respective protective sheating of the set;

figure 7a illustrates a view that represents the sequence following that demonstrated above in figure 7, where the refill of such a device is duly prepared for the disposal;

figure 8 illustrates a structure where the

packaging containing the kit may hereby proposed be positioned in an organized manner; and

figure 9 schematically illustrates three accessories, that separately or jointly, may make up part of the kit, object of this invention patent.

Pursuant to what the above listed figures illustrate, the secretion suctioning device comprises a suctioning valve 1, defined by a body 2, provided with a chamber 3, where a selective obstruction device 4 is assembled, formed by a pin 5, triggered by upper button 6, which acts against the action of a spring 7.

The chamber 3 is comprised of a channel selector 71, below pin 5, which is intended to be occupied by the lower rim 72 of said pin, this condition occurs with the heating of the suctioning valve 1.

The angle between the chamber 3 and the connection 11 causes the o-rings 8 to always be under a sealed condition, with valve 1 both under triggering or rest conditions.

Pin 5, as it was referred to, has two sealing 8 o-rings, assembled under ring necking 9, assembled upper and lower to a passage opening 10, through which the secretion passes, during the vacuum application moment.

The suctioning valve 1

operating systems determines that it may be conveniently locked, which prevents pin 5 from being inadvertently triggered, accidentally communicating the vacuum in this device.

Figure 3 illustrates a condition in which said pin is found to be completely retracted, fact that determines the misalignment of its passage opening 10.

By this, for the vacuum to be communicated with the suctioning valve 1, pin 5 must be turned by 90 degrees, thus leaving its locked condition, which is determined according to the upper button 6, along body 2 of valve 1.

Body 2 of the suctioning valve is provided with a connection that acts for the vacuum line coupling (not illustrated), which is used to produce the secretion withdrawal from inside the device, said connection 11 incorporates a progressive staggering 12, a fact which allows the use of several vacuum line diameters.

Connection 11, as demonstrated on figure 3, crosses chamber 3 and is aligned with an internal channel 13, which crosses body 2 of suctioning valve 1.

Body 2 is further provided with an rim connection 14, provided externally with a thread 15, to which is threaded a binding element 16, used to produce the coupling of a interconnection component 17,

used to produce the plastic sheating 18 sheating.

The interconnection component 17, basically comprises three regions defined as anterior 19, median 20 and posterior 21, each one with a specific object. The anterior region 19, is provided with ring ribs 22, preferably in three, which act as a means of sealing, regarding the internal wall of the rim connection 14. The median region 20 incorporates an outlining external wall, with an adequate profile to the tight connection with the binding element 16, making possible the interconnection component 17 to be axially dislocated, thus producing its fixation along body 2 of the suctioning valve 1. The posterior region 21 incorporates a trunk configuration ending 23, which acts as an adequate place for the rim plastic sheating 18 positioning, being said ending 23 the place for the retention ring 24 positioning, which guaranties the sealing and tight positioning of the already mentioned sheating 18.

The interconnecting component 17 receives internally the ending of a probe 25, which depending on its gauge may be assembled or not on a tie rod 26, which has the object of allowing the use of probes 25 with more than a measure of external diameter.

For this reason, the tie rod 26 is provided with a standard external diameter, to allow its introduction into the interconnecting component 17, besides being also provided with two measure of internal diameter to receive the probe 25.

Probe 25, as illustrates figure 2, presents a graduation 27, which is representative of its total measure length, being that on said probe 25, is assembled a limiting and marking means 28, that may be dislocated along probe 25, and thus, along graduation 27, allow the operator to pre-determine the course of introduction of same into the patient.

The limiting and marking means 28, as it can be observed in enlarged detail on figure 2, is internally provided with a pair of opposed protuberances 29, which act to produce a relative locking effect on the external wall of probe 25. The pair of opposed protuberances 29 thus guaranties if necessary, the aplication of a determined effort value to produce the dislocation of the limiting and marking means 28 along the probe 25.

As it can be concluded by the observation of figures 2 and 4, probe 25, crosses frontally, a terminal 30, provided with a casing 31, where a set of sealing rings 32 is assembled, said set being formed by two stiff rings 33, among which is assembled a flexible ring 34.

The casing 31 is closed by a component 35, which adequately presses the ring set 32, and also acts as a fixation place for the plastic sheating anterior rim 18, being that, for the latter object, it is provided in said component 35, a trunk ending 36, with identical configurations of the other trunk ending 23.

The trunk ending 36 receives a retention ring 37, identical to the other retention ring 24, assembled on the opposed rim of the plastic sheating 18.

The terminal 30 is provided with an instillation route 38, defined by an radial tubular projection 38', provided with a diaphragm 73, being that said route 38 begins at the wall of terminal 30, and receives the coupling from a tubular sector 40, which incorporates a closing cap 41.

Terminal 30 is provided with a connection 42, which externally receives a tightering element 43, used to produce body 44 coupling with a sphere valve 45.

The tightering element 43 stays on a thread 46, incorporated into a tubular projection 47, provided on sphere valve 45 on body 44.

The sphere valve 45 on body 44 is divided into two portions 48 and 49, each one incorporating half of chamber 50, which covers the sphere shaped element 51, which is formed by a central section 52, provided with a transversal channel 53 and with two supplementary sections 54.

The sphere shaped element 51 is driven by an upper external handle 55, which can be turned along a 90 degree range between two basic positions, which determine whether the transversal channel 53 and sphere valve 45, from valve body 44 longitudinal geometric

axis are aligned or not.

The sphere valve 45 isolates the internal environment, where probe 25 is located, allowing or not its passage towards patient/ventilator connection 56.

Sphere valve 45 is provided with a color code which eases its operational condition visualization, i. e., whether open or closed for probe 25 passage, said color code is defined by the fact that central section 52 presents a different coloration from the two additional sections 54. A preferred combination of colors define central section 52 from the sphere shaped element as green, and corresponding additional sections 54 as red. Such a color combination allows visualizing when the sphere valve is open or closed, being that, on its open position, central section 52, as green, stays in alignment with the sphere valve longitudinal geometric axis, on the other hand, on its closed position, the longitudinal sector keeps a transversal positioning regarding the valve body, while the supplemantary sections 54 become aligned with the longitudinal geometric axis mentioned above.

The patient / ventilator connection 56 is provided with a shift 57, which receives the connection line that communicates the ventilation equipment (not illustrated), said connection 56 is further provided with another connection 58, which is connected to the patient's coupling tube.

Shift 57 is incorporated so

that it presents an inclined angle that causes the maintenance of a non-turbulent laminar air flow, a especially ideal condition, from the point of view of the patient's vital signs.

As it is well illustrated by figure 4, the patient / ventilator connection 56 further incorporates sealing rings of the o-rings type, assembled on corresponding terminals 61.

On said figure 4, it is possible to notice that the air flow provided by the ventilation device does not find any kind of obstacle on its pathway, being that, upon arriving at connection 58, it is provided with a round wall sector 62, which deviates the entrance angle of such flow in a smooth a progressive manner, causing said flow to proceed with no turbulence towards connection 58 longitudinal geometric axis.

The patent further foresees besides the described device characteristics, the assembling of a set or kit 63, which comprises a package 64 that covers, besides the device unit mentioned, elements that help in its disposal after use, i. e., a plastic sheath 65 and a tube 66, the latter used to connect both rims of the device refill, as illustrated in figures 7 and 7a.

Packages 64 presents defined spaces divided by divider walls 67, allowing each covered element to occupy, in a organized manner, a previously studied place, as illustrated on figure 6.

The proposed kit is also provided with a structure 68, where a determined number of packages 64 can be adequately stored, as demonstrated on figure 8.

Structure 68 is provided with one or two parallel horizontal bars 69, that act as a hanger for packages 64, said structure 68 is further provided with a frontal panel 70, schematically illustrated in detail in figure 8, where all of the instructions for use of the proposed device are located.

Figure 9 illustrates a schematic view of three accessories that individually or jointly may make up part of the proposed kit, said accessories being able to occupy, for instance, the space E, indicated with a dotted line on the packaging, which is specifically demonstrated in figure 6.

Figure 9 accessories comprise a endotracheal tube fixture F, a humidifying filter F' and a secretion collector flask F''.

CLAIMS

1. "SECRETION SUCTIONING DEVICE FOR INTUBATED OR TRACHEOSTOMIZED PATIENTS", characterized in that it comprises a suctioning valve (1) defined by a body (2) provided with a chamber (3), where a selecting obstruction device is assembled (4), formed by a pin (5) triggered by an upper button (6), which acts against the action of a spring (7); the chamber (2) comprises a channel selector (71) below pin 5, which is designed to be occupied by said pin inferior rim (72), such condition occuring when suctioning valve is triggered (1), being that the angle between the chamber (3) and a connection (11) causes the o-rings (8) to always be in a sealed position, either the valve (1) being under its triggering or rest condition; the pin (5) is provided with ring neckings (9) on which the sealing o-rings are assembled (8), which are assembled above and below a passage opening (10) through which the secretion passes in the vacuum application moment; such a device is provided with an internal channel (13), that crosses the suctioning valve (1) body (2), said body (2) is further provided with a rim connection (14) provided externally with a thread (15), to which is threaded a tightering element (16), used to produce the interconnection component (17) coupling, used to produce the plastic sheating (18) imprisonment, said interconnection component (17) basically comprises three regions defined as anterior (19), median (20) and posterior (21), each one of which with a specific object,

being that the anterior region (19) is provided with ring ribs (22) preferably in three, that act as a sealing means regarding the internal wall external connection (14); the median region (20) incorporates an outlining external wall, with an adequate profile to tightly bind the tightering element (16), allowing the interconnection component (17) to be dislocated axially, thus producing its fixation along the suctioning valve (1) body (2); posterior region (21) incorporates a trunk configuration ending (23), that acts as an adequate place for the plastic sheating positioning (18), being that said ending (23) the positioning place for a retention ring (24), that guaranties sealing and tight positioning of said sheating (18); the interconnection component (17) internally receives the rim of a probe (25), that, depending on its gauge may be assembled either on a tie rod (26), and has the objective of allowing probe use (25) with more than a external diameter measure; the device is further provided with a terminal (30), equipped with a casing (31), where a set of sealing rings (32) is assembled, which is formed by two stiff rings (33), between which a flexible ring (34) is assembled; said casing (31) is closed by a component (35) that adequately presses the ring set (32) and also acts as a plastic sheating anterior rim (18) fixture, being that for the latter object it is provided in said component (35), a trunk ending (36) with a configuration identical to the other trunk ending (23); the trunk ending (36) receives a retention ring (37), identical to the other retention ring (24), assembled on the plastic

sheating (18) opposed rim.

2. "SECRETION SUCTIONING DEVICE FOR INTUBATED OR TRACHEOSTOMIZED PATIENTS", as claimed in 1, characterized in that the suctioning valve (1) may be conveniently locked, which prevents the pin (5) from being inadvertently triggered, accidentally communicating the vacuum in said device.

3. "SECRETION SUCTIONING DEVICE FOR INTUBATED OR TRACHEOSTOMIZED PATIENTS", as claimed in 1, characterized in that the connection (11) incorporates a progressive staggering (12), which allows the use of varied diameters of vacuum lines.

4. "SECRETION SUCTIONING DEVICE FOR INTUBATED OR TRACHEOSTOMIZED PATIENTS", as claimed in 1 and 3, characterized in that the connection (11) crosses the chamber (3), and is aligned with an internal channel (13), that crosses the suctioning valve (1) body (2).

5. "SECRETION SUCTIONING DEVICE FOR INTUBATED OR TRACHEOSTOMIZED PATIENTS", as claimed in 1, characterized in that the tie rod (26) is provided with a external diameter standardized to allow the introduction into an interconnection component (17), in addition to being provided with two internal diameter measures to receive the probe (25), being able to use two different probe gauges with the use of the tie rod (26), and two other different gauges without the use of the above mentioned tie rod (26).

6. "SECRETION SUCTIONING DEVICE FOR INTUBATED OR TRACHEOSTOMIZED PATIENTS", as claimed in 1, characterized in that the probe (25) is provided with a graduation (27), which is representative of its measure length, being that on the above mentioned probe (25) a limiting and marking way (28) is assembled, which may be dislocated along said probe.

7. "SECRETION SUCTIONING DEVICE FOR INTUBATED OR TRACHEOSTOMIZED PATIENTS", as claimed in 6, characterized in that the limiting and marking means (28) is provided with opposed protuberances pair (29), which act in order to produce a relative locking effect on the external wall of the probe (25), said opposed protuberances pair (29) thus guaranties a determined effort value to produce the limiting and marking means (28) dislocation.

8. "SECRETION SUCTIONING DEVICE FOR INTUBATED OR TRACHEOSTOMIZED PATIENTS", as claimed in 1, characterized in that the terminal (30) is provided with an instillation route (38) defined by a radial tubular projection (38) that starts from the terminal wall (30), and receives the tubular sector coupling (40), which incorporates a closing cap (41); the terminal (30) presents a connection (42) that externally receives a tightering element (43), used to produce the coupling of sphere valve (45) body (44).

9. "SECRETION SUCTIONING DEVICE FOR INTUBATED OR TRACHEOSTOMIZED PATIENTS", as

claimed in 8, characterized in that the instillation route (38) is provided with a diaphragm (73).

10. "SECRETION SUCTIONING DEVICE FOR INTUBATED OR TRACHEOSTOMIZED PATIENTS", as claimed in 8, characterized in that the tightering element (43) acts on a thread (46) incorporated in a tubular projection (47) provided on the sphere valve (45) body (44); the sphere valve (45) body (44) is divided into two portions (48) and (49), each one of these incorporating half of the chamber (50) that covers the sphere shaped element (51), which is formed by a central section (52) equipped with a transversal channel (53), and by two supplementary sections (54); the sphere shaped element (51) is driven by an external and upper handle (55) which can be turned along an angular range of 90 degrees between two basic positions, that determine whether the transversal channel (53) is aligned or not with the longitudinal geometric axis of the sphere valve (45) body of the valve (44).

11. "SECRETION SUCTIONING DEVICE FOR INTUBATED OR TRACHEOSTOMIZED PATIENTS", as claimed in 10, characterized in that the sphere valve (45) has the function of isolating the internal environment in which it the probe (25) is found, allowing or not its passage towards the patient/ventilator connection (56).

12. "SECRETION SUCTIONING DEVICE FOR INTUBATED OR TRACHEOSTOMIZED PATIENTS", as claimed in 10 and 11, characterized in that the sphere

valve (45) presents a color code that eases its operational condition visualization, i. e., whether open or closed to the probe (25) passage.

13. "SECRETION SUCTIONING DEVICE FOR INTUBATED OR TRACHEOSTOMIZED PATIENTS", as claimed in 12, characterized in that the color code is defined by the fact that the central section (52) present a different coloring from the two supplementary sections (54).

14. "SECRETION SUCTIONING DEVICE FOR INTUBATED OR TRACHEOSTOMIZED PATIENTS", as claimed in 13, characterized in that in a preferred combination for the sphere valve (45) color code, the central section (52) of the sphere shaped element presents a green color, and the corresponding supplementary sections (54) present a red color.

15. "SECRETION SUCTIONING DEVICE FOR INTUBATED OR TRACHEOSTOMIZED PATIENTS", as claimed in 11, characterized in that the patient/ventilator connection (56) is provided with a derivation (57) that communicates the ventilating equipment, said connection (56) is further provided with another connection (58) which is connected to the patient's coupling tube.

16. "SECRETION SUCTIONING DEVICE FOR INTUBATED OR TRACHEOSTOMIZED PATIENTS", as claimed in 15, characterized in that the derivation (57) is incorporated in a manner as to present an inclination angle that helps maintain of a non turbulent laminar air flow.

17. "SECRETION SUCTIONING DEVICE FOR INTUBATED OR TRACHEOSTOMIZED PATIENTS", as claimed in 11, characterized in that the patient /ventilator connection (56) incorporates sealing rings o-rings type (60), assembled on corresponding terminals (61).

18. "SECRETION SUCTIONING DEVICE FOR INTUBATED OR TRACHEOSTOMIZED PATIENTS", as claimed in 11, characterized in that the patient /ventilator connection (56) incorporates a round wall sector (62) that deviates the air flow entrance angle in a smooth and progressive manner.

19. "SECRETION SUCTIONING DEVICE FOR INTUBATED OR TRACHEOSTOMIZED PATIENTS", as claimed in 1, characterized in that the valve (1) presents a anatomic and inclined shape, which provides better suctioning, with less fatigue for the operator, as well as total sealing of the system, being the latter aspect related to the tightering element (16) and the interconnection component (17), thus avoiding the secretion accumulation.

20. "SECRETION SUCTIONING DEVICE FOR INTUBATED OR TRACHEOSTOMIZED PATIENTS", as claimed in 1, characterized in that that such a device is provided with a triple sealing, through the rings (33) and (31), allowing a more effective sealing effect of the external part of the probe (25).

21. "KIT PROVIDED WITH A SECRETION SUCTIONING DEVICE FOR INTUBATED OR

TRACHEOSTOMIZED PATIENTS", intended for the assembly of a device for the tracheal secretion suctioning of intubated or tracheostomized patients, characterized in that said kit (63) is provided with a package (64) that covers, in addition to the suctioning device, elements that help in its disposal after use, those elements being a plastic sheating (65) and a tube (66), the latter being used to connect both device endings; package 64 presents defined spaces and divided by divisor walls (67), allowing each covered element to occupy a previous studied place.

22. "KIT PROVIDED WITH A SECRETION SUCTIONING DEVICE FOR INTUBATED OR TRACHEOSTOMIZED PATIENTS", as claimed in 21, characterized in that it presents a structure (68), where a determined number of packages (64) can be adequately stored, said structure (68) is provided with one or two parallel horizontal bars (69) that act as a hanger for the packings.

23. "KIT PROVIDED WITH A SECRETION SUCTIONING DEVICE FOR INTUBATED OR TRACHEOSTOMIZED PATIENTS", as claimed in 22, characterized in the structure (68) incorporates a frontal panel (70) in which the instructions are presented for use of such suctioning device.

24. "KIT PROVIDED WITH A SECRETION SUCTIONING DEVICE FOR INTUBATED OR TRACHEOSTOMIZED PATIENTS", as claimed in 21, characterized in that it is able to incorporate, separately or jointly, three accessories (F), (F') and (F''), that respectively

represent an endotracheal tube fixture, a humidifying filter, and a secretion collection flask, those being able to occupy a defined space (E) in the interior of the package (64).

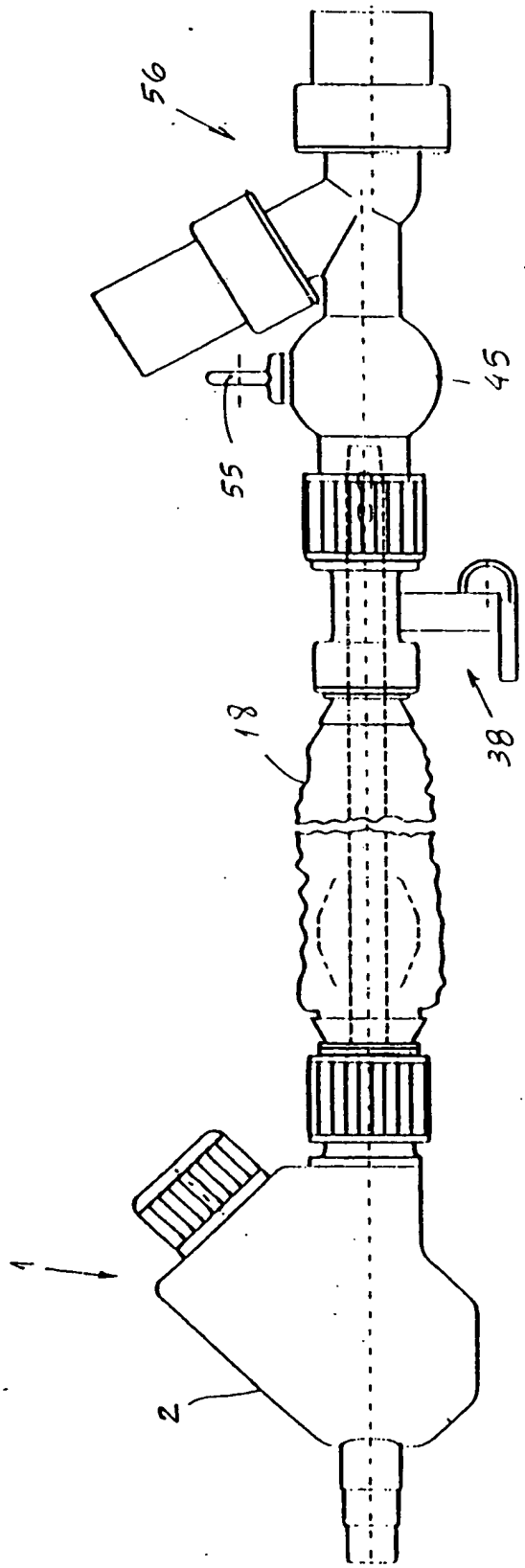
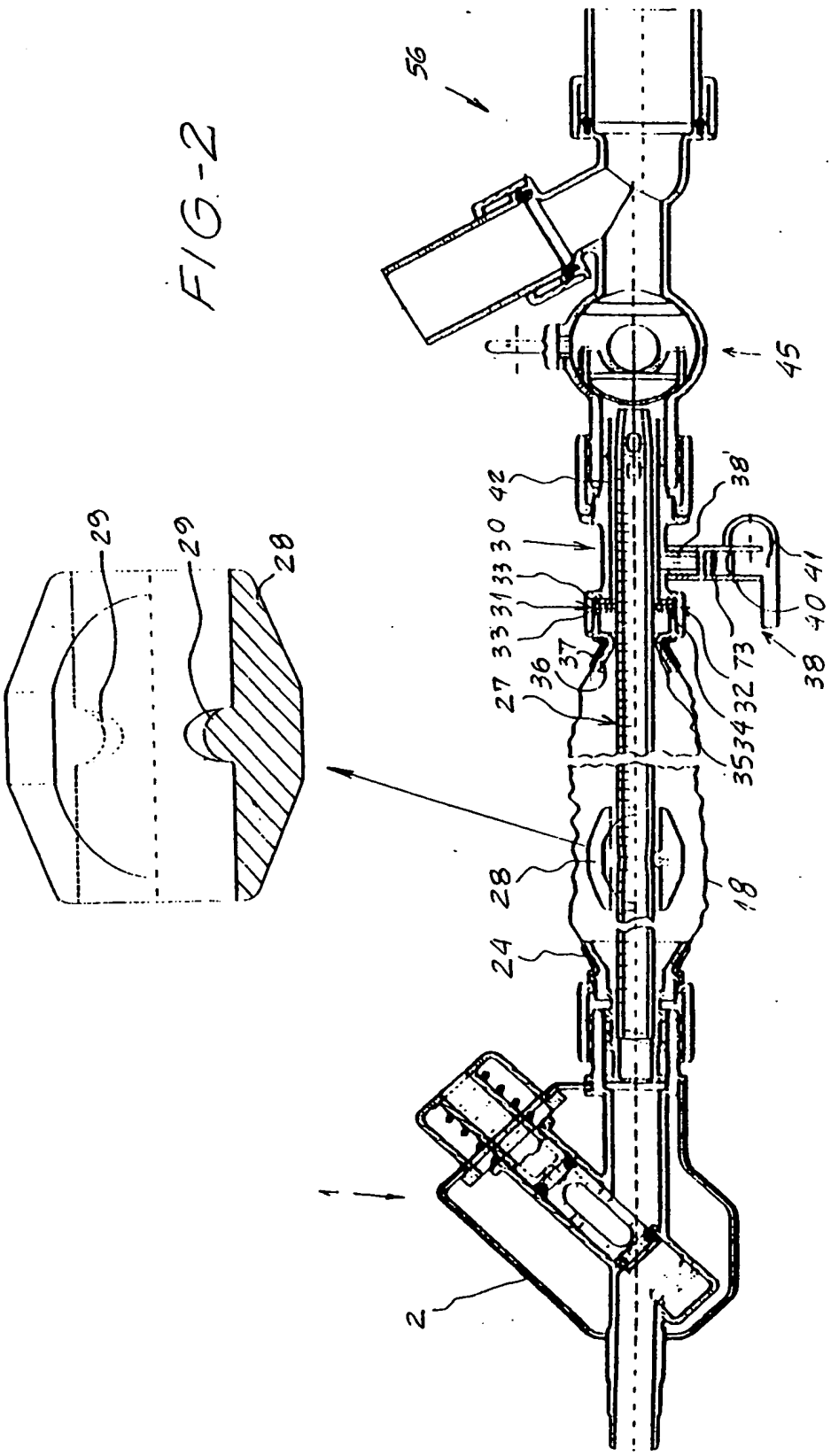


FIG. - 1

FIG-2


56
45
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38'
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33
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73
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41
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1
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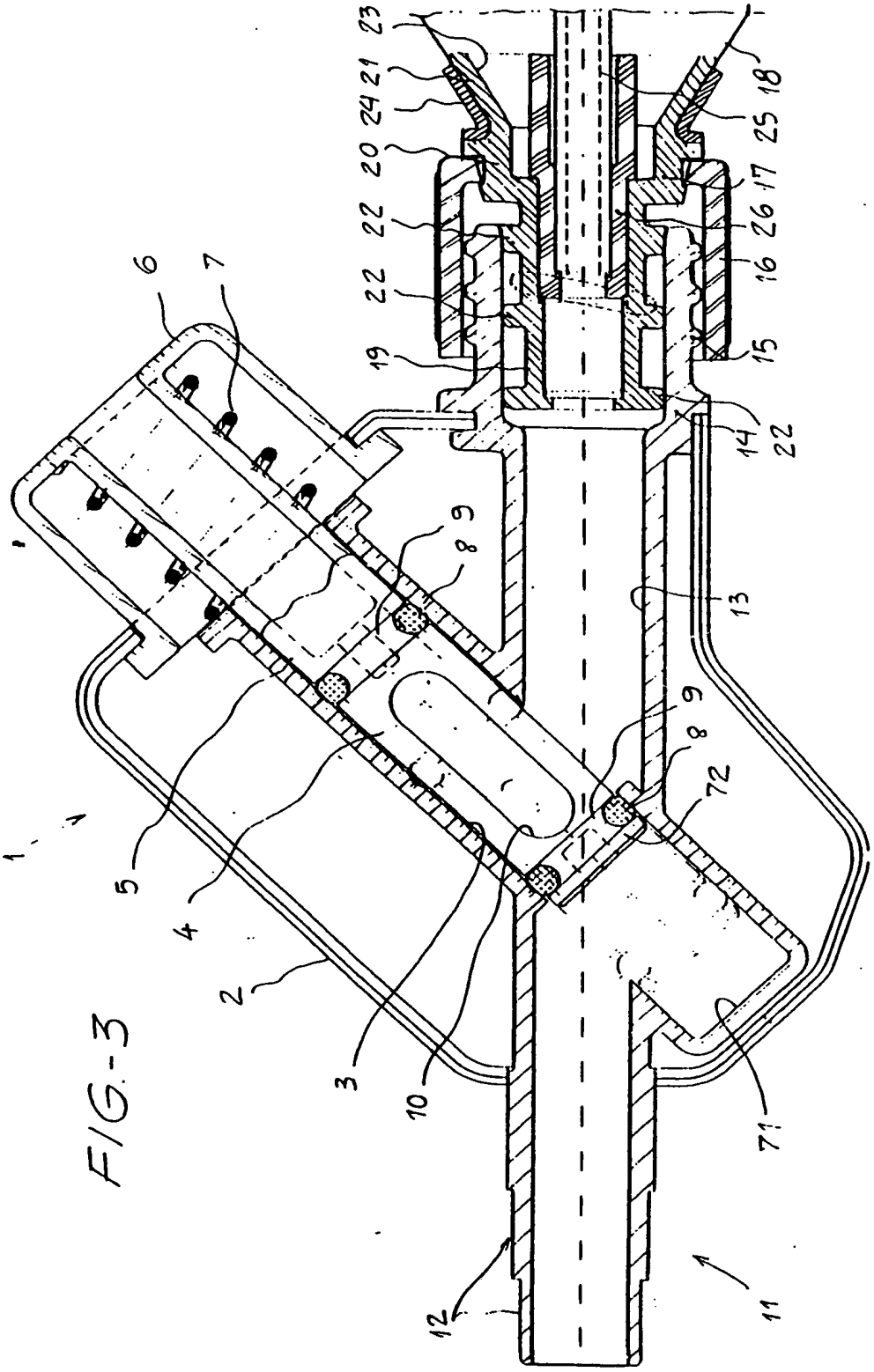
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11
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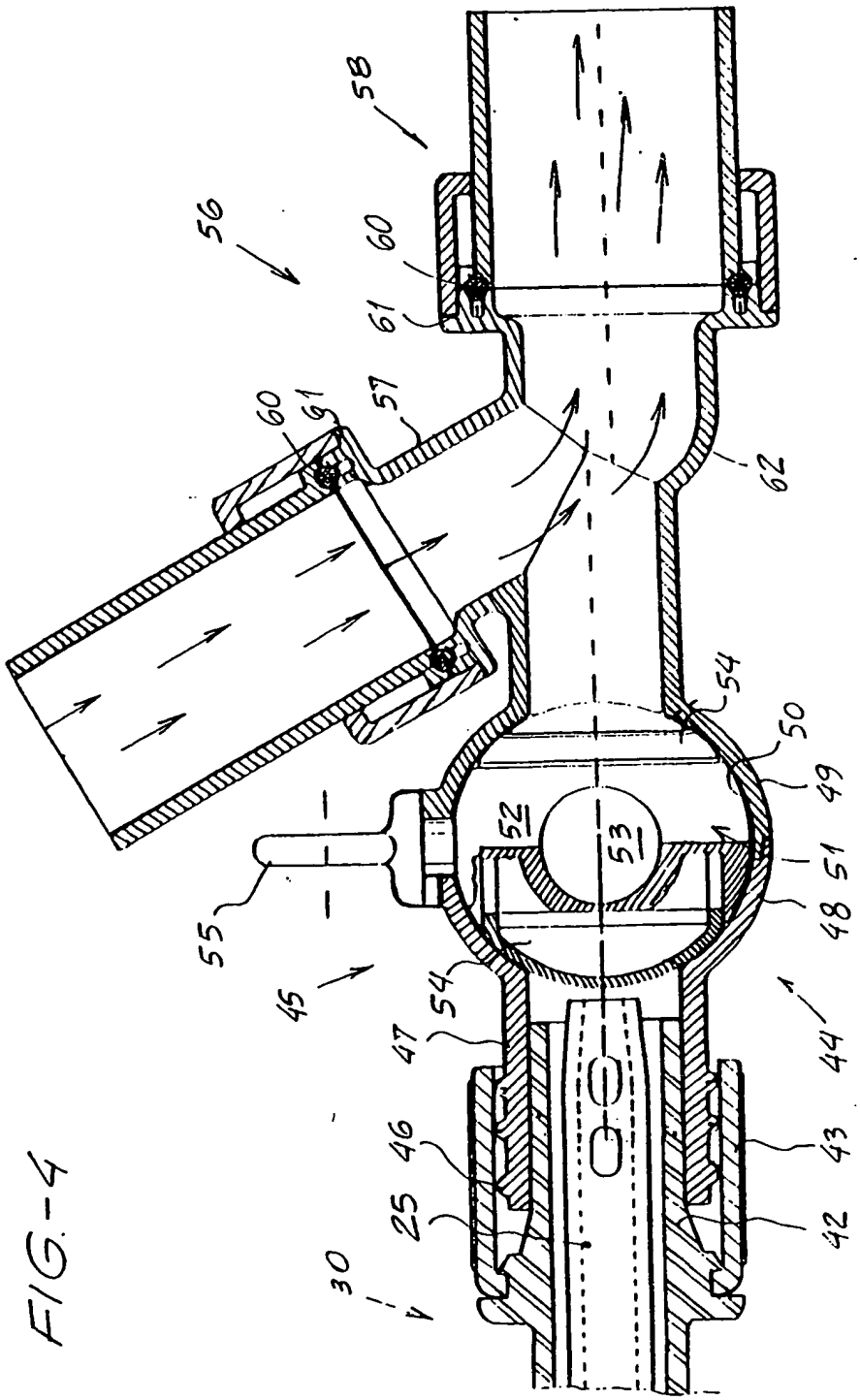
FIG-3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56
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FIG-4

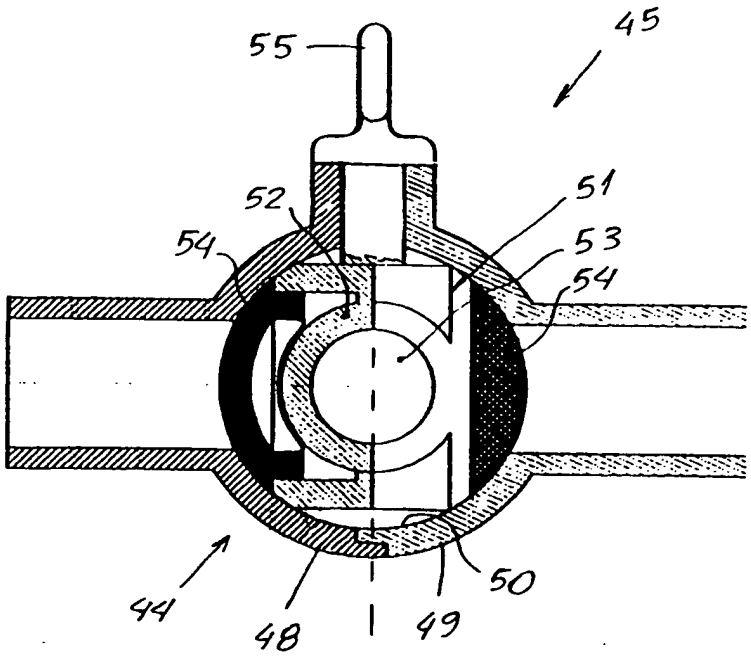


FIG. - 5

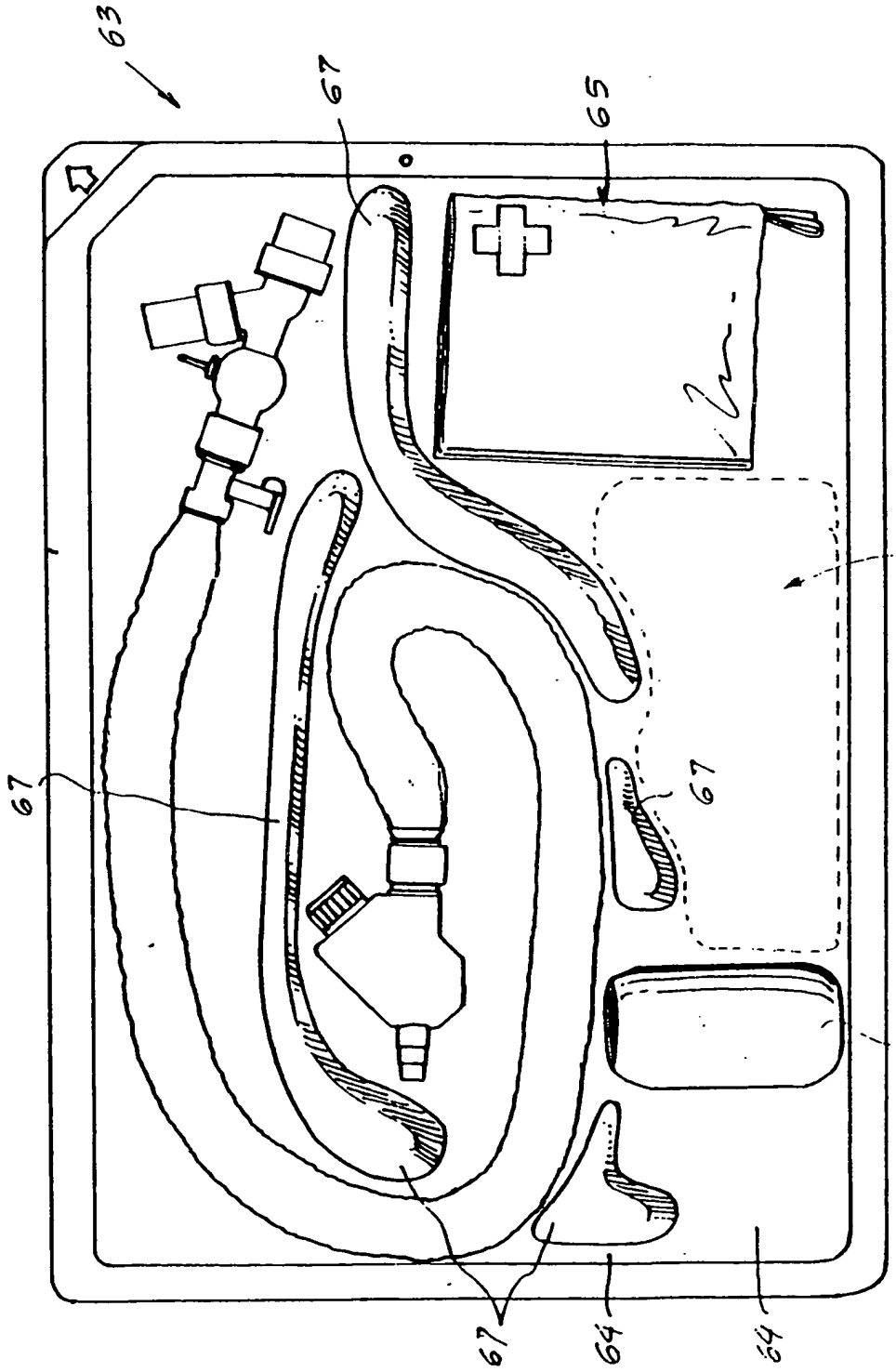


FIG-6 E

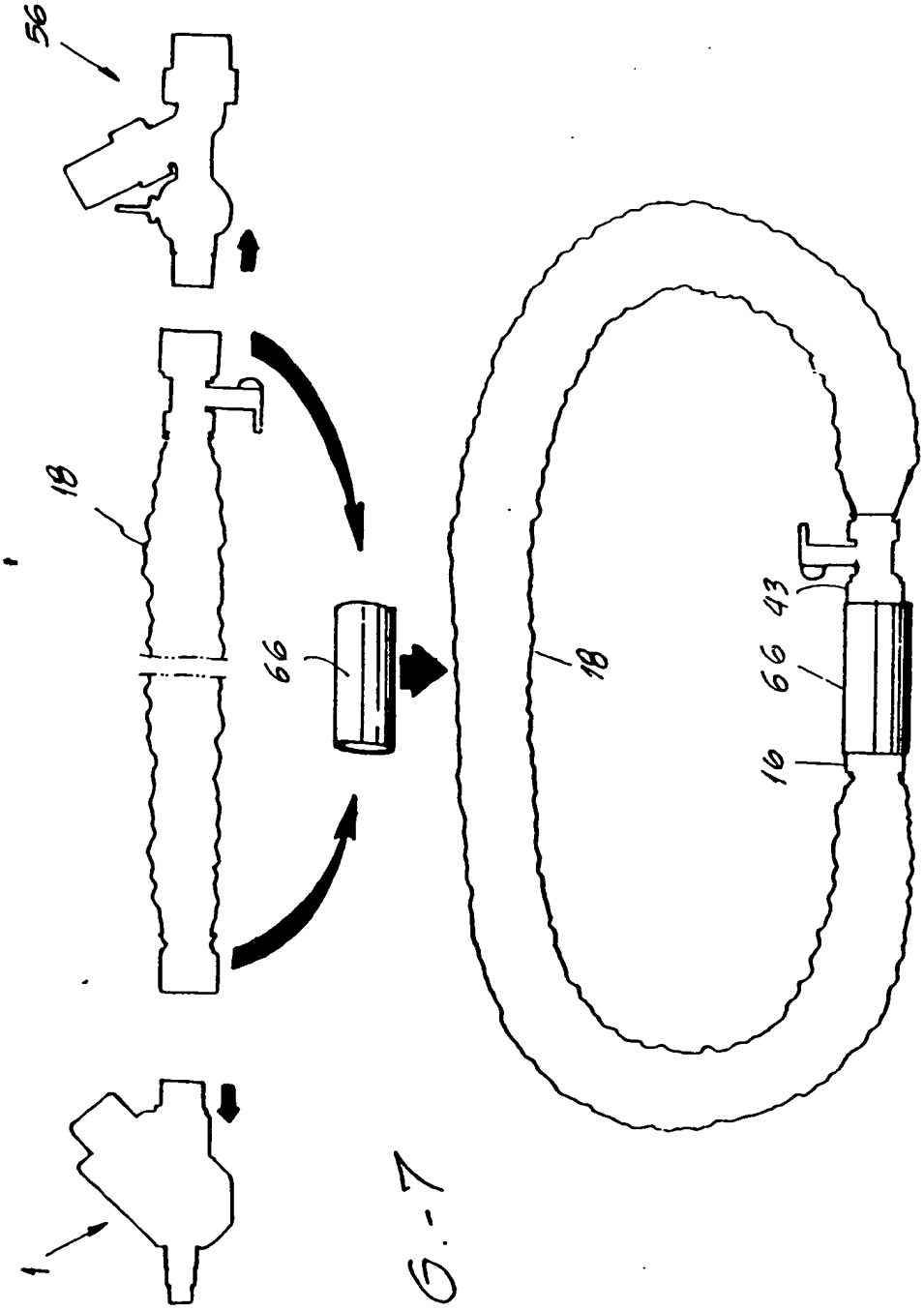


FIG.-7

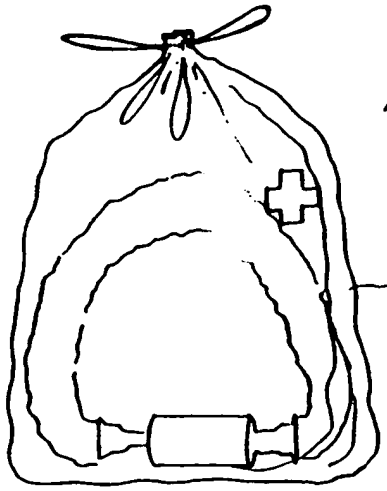


FIG.-7a

FIG.-8

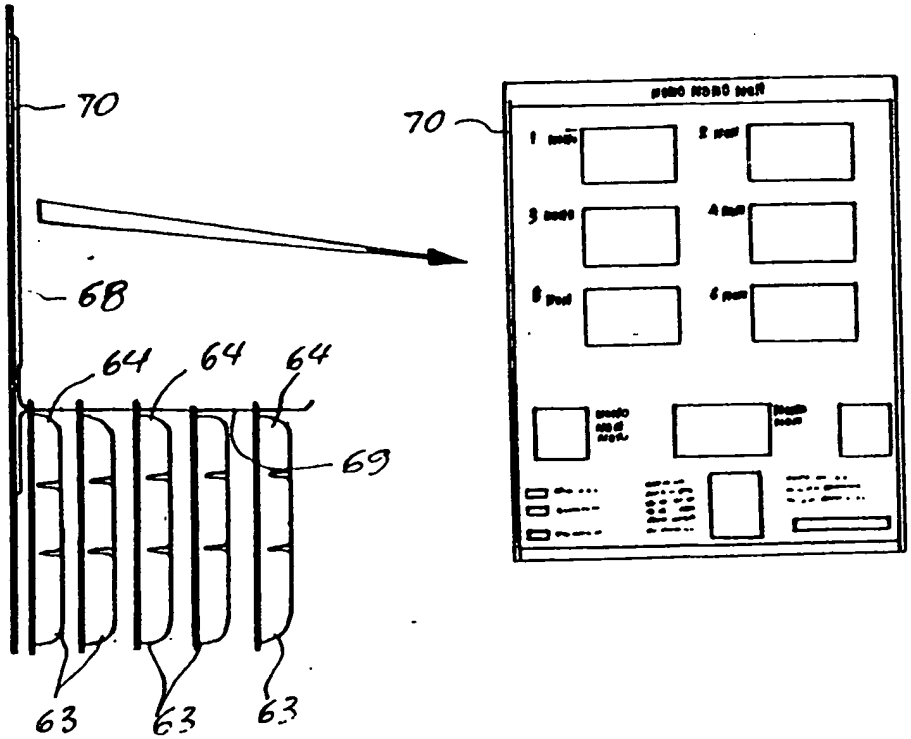
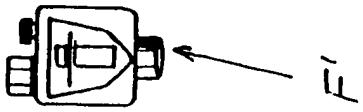
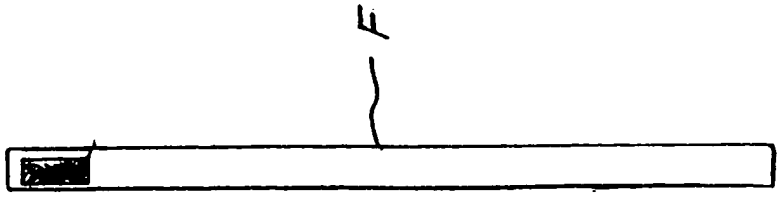


FIG.-9





INTERNATIONAL SEARCH REPORT

International application No.
PCT/BR99/00084

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61M 01/00
US CL :604/35
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 128/206.22, 207.14; 604/19, 22, 32, 35, 32

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 3,991,762 A (RADFORD) 16 November 1976.	1-3,4-11, 15-24
A	US 5,083,561 A (RUSSO) 28 January 1992.	1-3,5-11, 15-24
A	US 5,207,641 A (ALTON) 04 May 1993.	1-3,5-11, 15-24
A	US 5,255,676 A (RUSSO) 26 October 1993.	1-3,5-11, 15-24
A	US 5,354,267 A (NIERMANN et al.) 11 October 1994.	1-3,5-11, 15-24
A	US 5,490,503 A (HOLLISTER) 13 February 1996.	1-3,5-11, 15-24

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

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Date of the actual completion of the international search
17 JANUARY 2000

Date of mailing of the international search report
23 FEB 2000

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